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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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23552 7590 08/02/2010 MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903				
EXAMINER				
TREYGER, ILYA Y				
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08/02/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/590,229

Applicant(s)

RAJAN ET AL.

Examiner

ILYA Y. TREYGER

Art Unit

3761

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 5-7 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8 and 10-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1 and 8 are amended.
2. Claims 5-7 and 9 are canceled.
3. Rejection of claims 1-4, 8 and 10-13 under 35 U.S.C. 112, second paragraph has been withdrawn based on the amendment made to claim 1.
4. Claims 1-4, 8 and 10-13 are examined on the merits.

Response to Arguments

5. Applicant's arguments filed 09/22/2009 have been fully considered but they are not persuasive.

With regard to claim 1, Applicants argue that the combination of references does not disclose the claimed invention because the reference of Stack does not disclose the sleeve made of permeable material.

However, the reference of Stack discloses the reservoir that is a part of the device (page. 2, [0040], line 2) and comprises material that solves the same problem as that claimed by the Applicants, i.e. allows the substances to pass from the reservoirs into the surrounding tissue (page 2, [0039], lines 9-11).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to supply the apparatus of Rockey with the permeable material, an esophageal extension and a bowel extension, as taught by Stack in order to allow the substances to pass from the reservoirs into the surrounding tissue as motivated by Stack (page 2, [0039], lines 9-11).

6. Applicants further argue that the combination of references does not disclose the claimed invention because the inflatable chamber in the device of Rockey is not attached to the sleeve.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the inflatable chamber attached to the sleeve) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

7. Applicants further argue that the inflatable chamber of Rockey/ Stack is not attached to the exterior of the device.

However, Engel teaches an invasive device wherein the inflatable balloon 7 (fig. 1) is attached to the exterior of the device.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Rockey/ Stack with the inflatable chamber attached to the exterior of the device, as taught by Engel in order to improve fixation features utilizing the structure known in the art.

8. Applicants further argue that the combination of references does not disclose a toroid like inflatable chamber larger on one side as compared to the other side.

However, the inflatable chamber of Rockey necessarily obtains the asymmetric shape being placed under the pressure of surrounding tissues.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3761

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459

(1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-4, 8 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rockey (US 4,763,653) in view of Stack et al. (US 2003/0199991) and further in view of Engel et al. (US 6,119,697).

13. In Re claim 1, Rockey discloses a sleeve unit insertable in a natural body vessel (Abstract, lines 2, 3) capable of being used as a gastro-intestinal device (Col. 2, lines6-8), comprising:

a sleeve 51 (Fig. 9) that is a gastric bypass having an inlet A (Fig. 9) and outlet B (Fig. 9); and

an expandable inflatable balloon 50 (Fig. 9) attached to the gastric bypass (Col. 5, lines 64-68) fully capable of taking the asymmetric form, since it is made of flexible material.

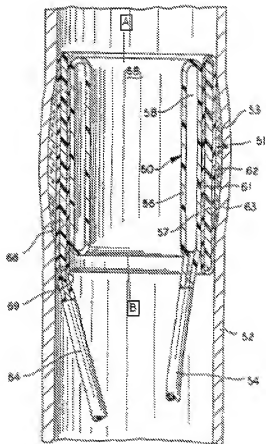
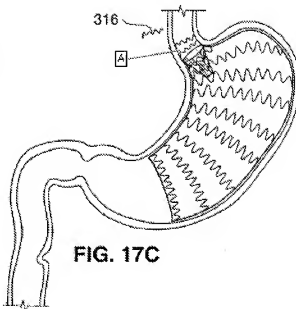
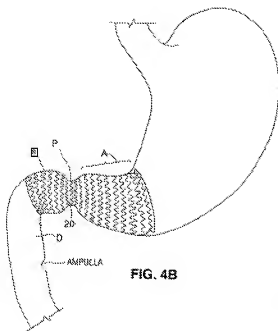


FIG. 9

Rockey does not expressly disclose the gastric bypass comprising a permeable material; an esophageal extension; and a bowel extension.

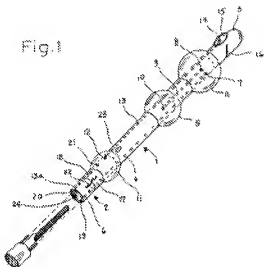
Stack teaches a gastric bypass comprising material that allows the substances to pass from the reservoirs into the surrounding tissue (page 2, [0039], lines 9-11); an esophageal extension A (Fig. 17C); and a bowel extension B (Fig. 4B).



It would have been obvious to one having ordinary skill in the art at the time the invention was made to supply the apparatus of Rockey with the permeable material, an esophageal extension and a bowel extension, as taught by Stack in order to utilize the bypass of the conventionally known type.

Rockey in view of Stack do not expressly disclose the inflatable chamber attached to the exterior of the device.

Engel teaches an invasive device wherein the inflatable balloon 7 (fig. 1) is attached to the exterior of the device.



It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Rockey/ Stack with the inflatable chamber attached to the exterior of the device, as taught by Engel in order to improve fixation features utilizing the structure known in the art.

Where a claimed improvement on a device or apparatus is no more than "the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement," the claim is unpatentable under 35 U.S.C. § 103(a). *Ex Parte Smith*, 83 USPQ.2d 1509, 1518-19 (BPAI, 2007)(citing *KSR v. Teleflex*, 127 S.Ct. 1727, 1740, 82 USPQ2d 1385, 1396 (2007)). Accordingly, Applicant claims a combination that only unites old elements with no change in the respective functions of those old elements, and the combination of those elements yields predictable results; absent persuasive evidence that the modifications necessary to effect the combination of elements is uniquely challenging or difficult for one of ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. § 103(a). *Ex Parte Smith*, 83 USPQ.2d at 1518-19 (BPAI, 2007)(citing *KSR*, 127 S.Ct. at 1740, 82

USPQ2d at 1396). Accordingly, since the applicant[s] have submitted no persuasive evidence that the combination of the above elements is uniquely challenging or difficult for one of ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. § 103(a) because it is no more than the predictable use of prior art elements according to their established functions resulting in the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement.

In regard to limitation “an esophageal extension comprising one or more flaps”, Rockey in view of Stack do not expressly disclose the one-way flap valve located in the esophageal extension of the device.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to supply the esophageal extension of the device with the one-way valve, since the constrictio phrenica (natural gastroesophageal flap valve) has been affected by the device, wherein it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the one-way valve in the form of flap valve, since it was known in the art that a valve having a hinged flap permitting flow only in the direction in which the flap opens (See *Dictionary.com Unabridged Based on the Random House Dictionary*, © Random House, Inc. 2009) (**MPEP 2144.03 (A-E)**).

14. In Re claims 2 and 8, Rockey discloses the gastric bypass comprising the flaccid gastric bag, since the sleeve (sheath) is disclosed as formed of flexible material (Col. 3, line 33).

15. In Re claims 3 and 10, Rockey discloses the invention discussed above, but does not expressly disclose the device having ribs facilitating collapse of the tube in the absence of compressive forces.

Stack teaches the gastric bypass comprising radially extending tabs 13 (Fig. 16B) that are ribs (claim 10) facilitating collapse of the tube in the absence of compressive forces (page 3, [0045], lines 1-6).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Rockey with the tabs, as taught by Stack in order to facilitate collapse of the tube (page 3, [0045], line 2).

16. In Re claims 4 and 13, Rockey discloses the invention discussed above, but does not expressly disclose the device formed of a polymeric sleeve with nitinol struts embedded in the sleeve material.

Stack teaches the device formed of a polymeric sleeve with nitinol struts embedded in the sleeve material (See page 4, [0060], lines 8-10), wherein the wire is disposed helically (claim 13).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Rockey with the nitinol struts, as taught by Stack in order to provide the device with the additional rigidity.

17. In Re claims 11 and 12, Rockey in view of Stack disclose the invention discussed above, as applied to claim 3, but do not expressly disclose the particular disposition character of the ribs.

Since Applicant did not state that such disposition character serves any specific purpose or performs any specific function other than the function disclosed in Stack, i.e. facilitating collapse of the tube, such disposition character is the matter of the obvious design choice, and therefore it would have been obvious to those skilled in the art at the time the invention was made to dispose ribs helically or longitudinally as an obvious design choice, and as such it does not impact the patentability of claims.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILYA Y. TREYGER whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ilya Y Treyger/
Examiner, Art Unit 3761
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